

Exhibit H

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION

CIVIL ACTION NUMBER:

1:19-md-02875-RBK-KW

STATUS CONFERENCE
(Via telephone)

Wednesday, March 24, 2021
Commencing at 11:00 a.m.

B E F O R E: SPECIAL MASTER,
THE HONORABLE THOMAS I. VANASKIE

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1 (ALL PARTIES VIA TELEPHONE, March 24, 2021,
2 11:00 a.m.)

3 JUDGE VANASKIE: We may still have others joining,
4 but I think we can get started.

5 Mr. Slater, are you comfortable proceeding now?

6 MR. SLATER: Yes, Your Honor, thank you very much.

7 JUDGE VANASKIE: All right. Mr. Goldberg, are you
8 comfortable proceeding now?

9 MR. GOLDBERG: Yes, Your Honor, I believe so. I
10 believe all of defense counsel are back on.

11 JUDGE VANASKIE: Okay. We'll give it another minute
12 or two.

13 All right. We will start now and we'll start with my
14 apology. This snafu is my fault. On March 4th, I received an
15 e-mail from Loretta Smith asking whether we could change this
16 CMC from March 24th to March 31st, due to the unavailability
17 of Judge Kugler today, and I said, of course, and then
18 proceeded to forget about it and that's why this happened.

19 So there will be a notice going out for a CMC for
20 next Wednesday, March 31st, at 10:00 a.m., but I was hoping we
21 could have dialogue now with respect to some other significant
22 matters that have been raised in the letters that I received
23 yesterday.

24 With that said, again, I'm sorry, because the mess-up
25 was on my end and we'll try to make sure we don't do this

1 again.

2 I wanted to proceed with the matters that are within
3 my bailiwick that are set forth in the letters that we
4 received yesterday.

5 MS. GOLDENBERG: Judge, this is Marlene Goldenberg.
6 I'm so sorry to interrupt. I just wanted to confirm, there
7 are a number of plaintiffs' counsel on the phone who are here
8 because of plaintiff fact sheet deficiencies, and typically,
9 that is an issue addressed with Judge Kugler.

10 Would it be okay if I told them they were all right
11 to hang up the phone?

12 JUDGE VANASKIE: Yes, yes. Ms. Goldenberg, they are
13 free to hang up the phone, that will not be addressed on this
14 call, but will be addressed next Wednesday in the call when
15 Judge Kugler's available.

16 MS. GOLDENBERG: Thank you very much.

17 JUDGE VANASKIE: Thank you for letting me know that.
18 All right. We'll continue to proceed then.

19 I wanted to pursue this matter in the order of the
20 items that were listed in Mr. Slater's letter of yesterday,
21 but there were three other issues that I was hoping we could
22 address.

23 One, I flagged for you earlier this week, and that is
24 the work product assertions that have been -- and
25 attorney/client privilege assertions that have been raised

1 with respect to third-party subpoenas served on ToxRox, and I
2 wanted to get a clarification on this because the other
3 party's name has sometimes been typed out as Meridian and
4 other times as Meridan. So I didn't know if it was Meridian
5 or Meridan, and I just wanted to get clarification on that.

6 MR. FELDMAN: Good morning, Your Honor, this is Ethan
7 Feldman on behalf of the Aurobindo defendants. It is Meridan.

8 JUDGE VANASKIE: Okay. All right. So I did want to
9 talk about that matter later in our conference call. I wanted
10 to talk about the issue of whether documents withheld as
11 unresponsive are responsive, and I have sent out an e-mail
12 today, a list of the rows of the documents that I have, using
13 a random number generator, identified as documents that should
14 be produced for in-camera review, but I wanted to have a brief
15 discussion about that first, hopefully.

16 If you're caught unaware or unprepared, we can always
17 postpone that discussion to next week.

18 And then, finally, at the conclusion of going through
19 the matters on counsel's letters, I wanted to get an
20 understanding of the outstanding issues before me and get your
21 sense of what I should prioritize.

22 But starting off with Mr. Slater's letter of
23 March 23rd, I wanted to start there. I am concerned that we
24 continue to have substantial discovery issues with respect to
25 production of documents, but there's no avoiding it, so I'd

1 like to start there, and Mr. Slater, I'll give you the
2 opportunity to be heard first with respect to Hetero discovery
3 status.

4 MR. SLATER: Thank you, Your Honor. And I'm going to
5 do this. This is Adam Slater for the record, and I'm going to
6 do this in as a condensed fashion as possible taking into
7 account, you know, the timing issues. I think I have a
8 solution to how do we get to where we need to get to.

9 So we've cataloged for Your Honor our concerns over
10 the course of the last several weeks, and Hetero has provided
11 their responses, and in their most recent submission to Your
12 Honor in yesterday's agenda letter, Hetero essentially is
13 representing now that they have completely complied with all
14 of their production obligations.

15 So, you know, from that starting point, there's two
16 things I'd like to submit to Your Honor.

17 One, there are still submissions that we have been
18 discussing in this process and requests for information and
19 documents that have not yet been addressed even by the agenda
20 letter from Hetero yesterday.

21 For example, as they've acknowledged to us, these
22 e-mails, just in the last 24 hours, they are still searching
23 to try to find and identify e-mails and other documents
24 surrounding the revisions and the preparation of these
25 standard operating procedures, the quality manuals and their

1 other quality booklets, because we basically have nothing
2 showing the drafting, the back and forth you would expect to
3 see, and the decisionmaking.

4 Second, we've asked multiple times and been told we
5 would be provided a list of the applications, the databases,
6 the structured databases, the share points and other software
7 that they have now collected documents from, and identified
8 through the interview process with their client, which they're
9 required to perform in order to produce ESI.

10 We've asked for that multiple times. It's not been
11 produced, along with confirmation that all of the responsive
12 documents from those sources have been provided.

13 We also are waiting for audit reports to be confirmed
14 as having been provided in full. Master SOP indexes, FDA
15 meeting notes and compliant-production indexes that actually
16 list all of the custodian Bates ranges.

17 So those are some examples of things that we have not
18 -- that were not addressed to Hetero's letter yesterday.

19 No. 2, Hetero had made a representation they have
20 completed production of the various categories of documents
21 they listed in their agenda letter. One of them, I'll just
22 note for the record, and we're going to have to now look at
23 their production and discuss with them further, Analyst Labs
24 which is a third party that Hetero agreed to produce documents
25 for. The production is still very questionable to us and I'm

1 just stating that for the record. It doesn't have to be
2 resolved today, but there are three documents relating to
3 Valsartan testing, and the rest relates to Losartan.

4 We find that to be difficult to understand or to
5 believe that can be complete. It may still be amended data or
6 production issue, but we will have to figure that out over the
7 next week.

8 The balance of the productions that were made, many
9 of them were made yesterday. Some of the key productions
10 where they're claiming they've now completed their production,
11 we have to obviously review those, review the overlay files
12 and make sure they are functional and correct, et cetera.

13 So what I would suggest, Your Honor, is this. Since
14 we haven't even had an opportunity to see the documents,
15 because they're just being loaded since last night, I would
16 suggest this. We are going to go through everything they've
17 produced. We have put them on notice of the ongoing issues,
18 and if Hetero wants to stand on saying they've produced
19 everything, despite our ongoing concerns and knowing that we
20 have raised issues that haven't been raised, and subject to
21 our review of their documents, my sense is that next week's
22 conference may be fortuitous that we've been kicked forward a
23 week, because we would like to then be able to present in
24 definitive fashion where we stand, and if despite the
25 representation from Hetero in their agenda letter that it

1 turns out they have not completed production and material
2 documents and information remain outstanding, I think at that
3 point we're going to have to come to an understanding with
4 Your Honor as to what remains outstanding and what the
5 appropriate way forward is, including potential
6 litigation-wide sanctions, including what we're going to do
7 with depositions.

8 Because as Your Honor appreciates, we can't keep
9 putting off depositions forever.

10 If it turns out that the productions are up to date
11 and that the other issues that I've listed and the other
12 issues we've been discussing get resolved by next Wednesday,
13 then we will be all the happier and we will then be able to
14 move forward with the depositions.

15 JUDGE VANASKIE: All right. Very well. Thank you,
16 Mr. Slater. Who will be addressing this for Hetero?

17 MR. SHAH: Good morning, Your Honor, this is Nakul
18 Shah on behalf of Hetero Labs and Hetero Drugs. I just wanted
19 to make one quick clarification with respect to plaintiffs'
20 statement that our agenda letter indicated that all
21 productions are complete.

22 It's actually not what our agenda letter stated. We
23 stated that we are complete with respect to the Analyst Lab
24 production, and additionally, that we have produced all of the
25 SOP-related documents that plaintiffs have requested.

1 So notwithstanding that point, Your Honor, I just
2 wanted to emphasize that Hetero's been working diligently to
3 address each and every point that plaintiffs have raised with
4 respect to our document productions.

5 As we've stated in our last status letter to Your
6 Honor, we transmitted several overlay files to correct
7 metadata deficiencies, we've provided updated privilege logs.
8 We've provided specific data that the plaintiffs are
9 requesting. We dedesignated consensual documents that
10 plaintiffs requested, and we made two productions with respect
11 to Analyst Labs.

12 Since that time, we've made additional supplemental
13 document productions of -- plaintiffs are requesting. We've
14 additionally provided a final cast of characters. We've
15 remedied additional metadata deficiencies and we've produced
16 the particular documents that plaintiffs have previously
17 stated were particularly relevant and important in order to
18 proceed with depositions. Which are versions of SOP-related
19 documents, in addition to site master files and quality system
20 manuals and master SOP indexes.

21 All of these documents have been produced to
22 plaintiffs and we're working diligently and tirelessly to
23 ensure that we address each and every point that plaintiffs
24 have raised.

25 What remains now is a very narrow discrete set of

1 outstanding issues that Hetero is confident that we can work
2 with plaintiffs to remedy quite expeditiously.

3 We believe that we've made significant progress since
4 our last status letter to the Court, and we don't believe that
5 it would require significantly more time in order to address
6 the outstanding issues.

7 JUDGE VANASKIE: Well, I'm encouraged by that report,
8 and as Mr. Slater indicated, many documents were received just
9 yesterday.

10 I agree with you, Mr. Slater, that you should review
11 those -- the latest production and then make a determination
12 as to whether it is complete and what issues remain
13 outstanding. I understand there may be some issues that are
14 outstanding and there is a commitment to continue to have a
15 dialogue to resolve those disputes, but hopefully they can be
16 resolved by next Wednesday so at least we can get these
17 matters addressed today and keep the matter moving, hopefully,
18 with final resolution coming next Wednesday.

19 I certainly wouldn't relish the receipt of sanctions
20 motions for discovery problems, but if it comes down to that,
21 it has to come down to that. So I'm hoping we can avoid that,
22 but understand that that might not be avoidable.

23 But I'll encourage you to continue to work together
24 to get this matter resolved. I know it's extremely complex
25 and extremely voluminous, but it needs to be done.

1 Anything else on Hetero, on this particular point
2 right now?

3 MR. SLATER: No, Your Honor, not for the plaintiffs.
4 Thank you for your guidance.

5 JUDGE VANASKIE: All right. Okay. Anything else
6 from Hetero?

7 MS. SHAH: No, Your Honor, thank you.

8 JUDGE VANASKIE: All right. Thank you.

9 The next item that I had was Aurobindo, and there's
10 many pages taken up in the plaintiffs' letter on Aurobindo.
11 Mr. Slater?

12 MR. SLATER: I'm going to hand this off, Your Honor,
13 to Marlene Goldenberg and --

14 JUDGE VANASKIE: Okay.

15 MR. SLATER: -- she will then handle this issue, and
16 I don't think I'll be handling too many other issues today, if
17 any, so I'll be handing off to my colleagues. Thank you.

18 JUDGE VANASKIE: Very well, thank you.

19 MS. GOLDENBERG: Good morning, Your Honor.

20 JUDGE VANASKIE: Ms. Goldenberg, good morning.

21 MS. GOLDENBERG: Yes. And so there is a lot in here,
22 and because it sounds like you've -- thankfully, we appreciate
23 you taking the time to read it, so I'm not going to rehash
24 everything in the letter. I'm just going to start with what
25 we're asking for in each section, and if you have questions,

1 I'll be happy to delve into why.

2 But the first thing that we're asking Aurobindo to do
3 is to search the noncustodial files that we've been asking
4 them to search for months now, because we've now taken a
5 deposition and found that there are at least three or four
6 shared drives as well as a number of software programs that
7 are regularly utilized by Aurobindo employees, and as we've
8 demonstrated in the last deposition, the only documents we had
9 received as to that custodian, all had a file path that shows
10 those documents were only from Outlook and were not searched
11 anywhere else.

12 We also determined that there were a number of
13 documents that were kept in paper form, and as we have no
14 documents that appear to have been scanned up for that
15 custodian, we also learned that were missing batch records,
16 for example, as well as all of the notebooks that that witness
17 regularly kept in the course of doing his job for Valsartan.

18 And so we're asking the Court to order Aurobindo to
19 search those shared drives to produce the paper files and to
20 produce the notebooks that that witness kept.

21 JUDGE VANASKIE: All right. I'll interrupt you just
22 for a minute now. I understand they've agreed to search the S
23 drive; is that right, S as in Sam?

24 MS. GOLDENBERG: Yep. My understanding is they've
25 only volunteered to search the S drive and not the others.

1 JUDGE VANASKIE: Okay. And who will be addressing
2 this issue on behalf of Aurobindo?

3 MS. HEINZ: Good morning, Your Honor, this is Jessica
4 Heinz for the Aurobindo parties. Ms. Marlene is --

5 JUDGE VANASKIE: Good morning.

6 MS. HEINZ: Good morning, Your Honor. That is not
7 totally accurate, Your Honor. I responded to Ms. Marlene that
8 we would search the S drive data. I did not refuse to search
9 any other of the other drives that she mentioned. I'm still
10 discussing that with my client. It's my understanding that
11 all of the proper noncustodial data sources were searched and
12 produced from, I'm working on going back to my client and
13 communicating Ms. Goldenberg's concerns to them, and I offered
14 to meet and confer with her about this later this week.

15 If Your Honor recalls, the last time we met on
16 March 10th, this issue was brought up by the plaintiffs and
17 Your Honor asked them to be more specific about the documents
18 that they believe are missing, and, you know, we appreciate
19 that they have now attempted to do so, but there has to be
20 time for us to evaluate this and have a meet-and-confer
21 process.

22 This was just raised since the last conference and
23 we're trying to go back and -- to make sure we're doing
24 everything that we, you know -- make sure that we're complying
25 with all of the requests and having a good faith

1 meet-and-confer process with the plaintiffs.

2 We hope we can discuss this with them later this
3 week, if not sooner than that, and report back to the Court
4 next week.

5 JUDGE VANASKIE: What about noncustodial sources?
6 Have you had a discussion on that particular issue,
7 Ms. Goldenberg?

8 MS. GOLDENBERG: Your Honor, just to clarify. These
9 are noncustodial sources and so these drives that were
10 discussed in our agenda letter are drives that are accessible
11 by all employees, and the reason that we've asked Ms. Heinz to
12 confirm that she searched all these noncustodial sources is
13 that, you know, our fears are being realized that Aurobindo
14 seems to be waiting to get caught, and I know about those four
15 drives. I don't know what other ones exist.

16 We have another deposition tomorrow, but, you know,
17 our hope is that Aurobindo is going to comply with the
18 discovery obligations, identify the relevant noncustodial
19 sources and produce those documents.

20 JUDGE VANASKIE: All right.

21 MS. HEINZ: Your Honor, I just wanted to say one
22 thing. I think it's a little improper to characterize what
23 we're doing as "waiting to get caught." I think that's
24 inappropriate. There's no sort of evidence that we have
25 engaged in any -- that we haven't produced what we should

1 have. We're engaged in this meet-and-confer process. We're
2 producing everything that we believe are responsive to the
3 requests, so I just wanted to clarify that I think that
4 statement is unfair and a little improper and unprofessional.

5 JUDGE VANASKIE: Do you want to respond,
6 Ms. Goldenberg?

7 MS. GOLDENBERG: Well, I think it goes without saying
8 that I disagree with the characterization of that, but I don't
9 want to belabor the point and take up more time on the record
10 about that, so I'll just return to my ask that, you know, we
11 get documents from these shared drives and that we get it soon
12 so that we can take meaningful depositions and not have to
13 take them again.

14 JUDGE VANASKIE: When I referred just now to
15 noncustodial sources, I was having in mind the items or
16 applications that you listed on the top of Page 5 of
17 plaintiffs' letter, Trackwise, Oracle, LIMS and QAMS.

18 Did you want to say anything about that,
19 Ms. Goldenberg?

20 MS. GOLDENBERG: Yes, Your Honor. So the witness
21 that we deposed, Mr. Doshi last week, testified that these
22 were all software programs where things like batch records and
23 standard operating procedures and other documents that he
24 needed to do his job to ensure that Valsartan was made
25 properly were housed in.

1 It sounds like this is where a lot of his work took
2 place, and so our ask, also, is that these systems be searched
3 for any relevant documents as noncustodial sources, not just
4 in relation to this one custodian, and that those documents be
5 produced promptly as well.

6 JUDGE VANASKIE: All right. And, Ms. Heinz, are you
7 endeavoring to do that?

8 MS. HEINZ: Your Honor, we have produced the
9 noncustodial documents responsive to the request. I believe
10 Ms. Goldenberg is misstating Mr. Doshi's testimony. They have
11 not filed a motion here. We're certainly happy to respond to
12 a motion, if they think that's necessary, but like I said, we
13 are endeavoring to engage in this meet-and-confer process with
14 them about this, and I am communicating their concerns to my
15 client, and we're happy to, you know, if there are any
16 disputes remaining, we're happy to address them next week at
17 the case management conference.

18 But I'll just say that, you know, just because
19 somebody testified -- and let me clarify one thing, Mr. Doshi
20 is a fact witness, he was not produced as a 30(b)(6) witness.
21 Just because a fact witness testifies that a computer drive
22 exists does not mean that it has responsive information that
23 should be produced here, and it doesn't mean that it hasn't
24 been searched.

25 So, you know, I just hope that we can continue to

1 engage in a meet-and-confer process to work -- to try and work
2 these things out so that the Court doesn't have to intervene
3 and issue any orders, because I am confident and hopeful that
4 we can reach a resolution just between the parties.

5 JUDGE VANASKIE: All right. Very well. Has there
6 been any effort to find out whether the notebooks that
7 Mr. Doshi talked about are available? Ms. Heinz?

8 MS. HEINZ: Yes, Your Honor, I've asked him to send
9 those to me and it's my understanding they may have been
10 received yesterday. I haven't had a chance to look at them
11 yet, but I will get those over to Ms. Goldenberg later today.

12 JUDGE VANASKIE: All right. Very well. Where do
13 things stand with respect to the hard drives that were sent to
14 India? Ms. Heinz, can you update us on that?

15 MS. HEINZ: Yes, Your Honor. So it's my
16 understanding as of yesterday, I heard that the FedEx package
17 was received in India, that copies were being made and we are
18 hopeful we will be getting those shipments soon.

19 JUDGE VANASKIE: All right. Ms. Goldenberg, do you
20 want to be heard on the hard drive issues? You asked for a
21 couple of -- you've proposed a couple of options here.

22 MS. GOLDENBERG: I have -- yes, Your Honor, thank
23 you. My understanding, and Ms. Heinz can correct me if I'm
24 wrong -- but what I heard her say just now was that the hard
25 drives had been received in India. Is that accurate, Ms.

1 Heinz?

2 MS. HEINZ: Yes. I'm referring to the replacement
3 hard drives that were sent when we were unable to try and get
4 the -- I believe the others are still held in Customs. I
5 haven't received any updates on those. The package via FedEx
6 was received March 18th and it should be on its way back, I
7 believe, which is why we're expecting to receive the shipments
8 soon.

9 MS. GOLDENBERG: So, Your Honor, I think, you know,
10 the problem with that is that these are empty hard drives and
11 these empty hard drives just made it to India. And what Ms.
12 Heinz -- what the rest of this process looks like is that they
13 then have to be -- the documents have to be loaded on to these
14 hard drives and then Aurobindo intends to mail them back,
15 which means they again have to go through Customs.

16 This is all -- the easiest way to get these documents
17 is by choosing Option A or Option B, or I think I called them
18 1 and 2 in our agenda letter. This is not hard, and it is
19 baffling, frankly, to the plaintiffs that this option has been
20 selected by the defendants, particularly when there is a court
21 order that these documents be produced in time. And with
22 these options available, I guess I'm just now at a loss for
23 why they haven't been taken, but we're asking the Court to
24 order that Aurobindo use FTP or Dropbox to get these documents
25 to them so that we can move forward.

1 JUDGE VANASKIE: Ms. Heinz, why are either option not
2 doable from Aurobindo's perspective; that is, purchase a
3 Dropbox account or transfer the data by FTP?

4 MS. HEINZ: It's my understanding from Aurobindo that
5 they have been unable transfer the data via FTP. I will say,
6 and this is just from my knowledge of FTPs and Dropbox, but
7 they are not very -- this is a lot of data that's being
8 transferred, and I believe there is a lot of security, cyber
9 security concerns transferring things via Dropbox.

10 But as far as Aurobindo goes, all the information
11 that I have is that they've been unable to transfer the data
12 via FTP.

13 MS. GOLDENBERG: Your Honor, if I could --

14 JUDGE VANASKIE: Yes, Ms. Goldenberg.

15 MS. GOLDENBERG: I'm going to call on Behram Parekh,
16 who is our resident CSI expert and I think he's going to chime
17 in here.

18 JUDGE VANASKIE: Very well. That would be helpful.

19 MR. PAREKH: Good morning, Your Honor, Behram Parekh.
20 I honestly cannot understand why FTP is not being used here.
21 I mean, we have regularly transferred hundreds of gigabytes of
22 data via FTP, based in our own practice and in other
23 litigations. Dropbox may not be as secure as direct FTP
24 transfer, however, that can be ameliorated by encrypting the
25 data before putting it on Dropbox and decrypting data on the

1 other end.

2 There are -- even without FTP, vendors have other
3 file transfer protocols that are available, that are more
4 secure, such as SFTP. I mean, there's numerous ways of
5 transferring this data that does not involve shipping hard
6 drives back and forth, and given the volume of data as Ms.
7 Heinz has stated, which is approximately one million
8 documents, it should not have taken more than a few hours to
9 transfer this data, at the most, six to eight. So it's mind
10 boggling that we're now a week and a half later and the data
11 is still supposedly sitting in India.

12 JUDGE VANASKIE: Anything else, Ms. Heinz?

13 MS. HEINZ: Your Honor, as stated in our position
14 statement, we are happy to provide an affidavit from KLD
15 Discovery regarding the events that transpired on the
16 shipments of the hard drive. That may be helpful for the
17 Court to hear -- for the Court to see, and we'd appreciate the
18 opportunity to submit that, if Your Honor will accept.

19 JUDGE VANASKIE: Well, I mean you can submit that,
20 but I'm going to order that you first try to transfer the
21 files via an appropriate file transfer protocol. I know
22 you've said you've tried and it hasn't been successful, but
23 I'm perplexed as to why that cannot be accomplished. And then
24 if it can't be accomplished by file transfer protocol, then I
25 think you should go use option one, encrypt the data and use

1 an account through Dropbox to transfer it. I think that takes
2 care of the security concerns, and I'm going to ask that that
3 be accomplished within seven days of today. You can give me
4 an update for our call next Wednesday, but it needs to get
5 done, and this is frustrating that it hasn't been done, and so
6 I will issue an order after the conclusion of this call to
7 that effect.

8 MS. HEINZ: Understood Your Honor. Thank you.

9 JUDGE VANASKIE: Thank you.

10 Now, the next issue I had with respect to Aurobindo,
11 Ms. Goldenberg, were the purchases from ZHP. Where does that
12 stand?

13 MS. GOLDENBERG: Yes, Your Honor, we detailed Ms.
14 Heinz about that, but haven't received a response. And so
15 just to cut to the chase on this one, our request is that
16 documents relate, those purchases from ZHP.

17 (Reporter asks Ms. Goldenberg to repeat.)

18 MS. GOLDENBERG: For once I think I actually had a
19 short sentence. Our request is just that we get these
20 documents relating to Aurobindo purchases from ZHP.

21 JUDGE VANASKIE: Ms. Heinz?

22 MS. HEINZ: Your Honor, I did not fail to respond to
23 Ms. Goldenberg. I told her that I am discussing this with my
24 client. I asked for a copy of the document that they
25 referenced, which was from a codefendant. They produced it to

1 me yesterday. This is something that they raised just, I
2 think it was last week. I'm happy to continue meeting and
3 conferring with them about this, as I said to Ms. Goldenberg
4 in my e-mail yesterday, or maybe the day before, I just, I
5 need to speak to my client about it.

6 And I -- and I haven't had any time to do that. I
7 mean, there needs to be a reasonable meet-and-confer process
8 here, and I would just ask for more time to do that so we can
9 happily -- I hope that we can get this resolved before the
10 next conference, but if we don't, that we give the Court an
11 update.

12 JUDGE VANASKIE: All right. Let's proceed on that
13 basis. I'll ask for an update by next Tuesday, so in advance
14 of Wednesday's conference call, in terms of where you stand
15 with respect to purchases from ZHP. Hopefully, you can have
16 that all resolved.

17 The next item on the Aurobindo list was missing
18 standard operating procedures. Ms. Goldenberg, where does
19 that stand?

20 MS. GOLDENBERG: Yes, Your Honor. This is one where
21 we sent Ms. Heinz an e-mail, I believe it was a week or two
22 ago, and once again, all we've gotten back from her is we'd
23 like to meet and confer and they've offered always after these
24 case management conferences and, you know, we don't have an
25 answer, so here it is on the agenda. But we would like them

1 to produce all of the standard operating procedures.

2 JUDGE VANASKIE: All right. Ms. Heinz?

3 MS. HEINZ: Your Honor, my clients on March 4th
4 produced 80,000 pages of standard operating procedures. I
5 received Mrs. Goldenberg's list of an additional 80 standard
6 operating procedures that she believed are responsive to the
7 request.

8 We are evaluating those and discussing them with my
9 client. I told Marlene that I believe we're going to be able
10 to reach an agreement on many of those. And I offered to meet
11 and confer if -- I don't even know if we'll have to have a
12 meet and confer because I'm hoping I'll have a production out
13 to her, a supplemental production, within the next week.

14 It's, you know, it's another thing they've raised
15 since the last conference. There just hasn't been that much
16 time to get through everything.

17 JUDGE VANASKIE: All right. Well, thank you. What
18 I'll ask is that you continue to see if you can work this out,
19 see if the supplemental production will include you said 80
20 SOPs that are being sought. See how many of those will be
21 produced, and I'll ask that in the status report you send to
22 me by next Tuesday you address this issue as well so we can
23 see where that stands.

24 And then the next Aurobindo issue deals with
25 privilege log challenges. And, Ms. Goldenberg, where does

1 that stand?

2 MS. GOLDENBERG: Yes, Your Honor, we have asked
3 Aurobindo to dedesignate a number of documents. As this
4 conversation started awhile back and then we held pursuant to
5 Your Honor's request that we get the cast of characters. We
6 now have the cast of characters and we sent Ms. Heinz
7 challenges and, you know, there are a lot of them, as you can
8 see, but the short way of summarizing where we're at right now
9 is that of the cast of characters only three people on it are
10 attorneys. And so our position is that Aurobindo should have
11 voluntarily dedesignated a lot of these documents themselves,
12 but as you heard Ms. Heinz say, she asked us to point out what
13 was missing and what's wrong, and so we've done that. And we
14 once again received a request from Ms. Heinz asking if we
15 could meet and confer later this week, but, you know, we've
16 got a deposition tomorrow, we have another one in two weeks,
17 and many of the documents here are relevant to Mr. Gorijavolu,
18 who is being deposed tomorrow, and Blessy Johns who is being
19 deposed in two weeks. And again, we really just need to move
20 this process forward.

21 JUDGE VANASKIE: Ms. Heinz?

22 MS. HEINZ: Yes, Your Honor. Mrs. Goldenberg is
23 referring to a letter that plaintiff sent me Friday night, and
24 we told her that we are evaluating it. We did not refuse to
25 cooperate with them on the meet-and-confer process. We

1 offered to meet and confer later this week once we have a
2 chance to go through everything that they have identified in
3 their letter which they essentially appears to have copied and
4 pasted into their position statement.

5 This is another thing similar to the SOPs where we're
6 hopeful we can, you know, work some -- we can -- once we
7 review everything, you know, we've agreed to go back and
8 re-review everything and see if there's anything that we can
9 agree to produce.

10 I think that Ms. Goldenberg is misstating the legend
11 of our SOPs. I believe there are many more legal personnel on
12 that than just three.

13 So it's just another one of those things that we need
14 more time to evaluate and talk to our clients about, and we're
15 confident that we're going to be able to work something out
16 with the plaintiffs. We just -- we need a little bit more
17 time to finish that meet-and-confer process.

18 MS. GOLDENBERG: Your Honor, if I could just respond
19 to that.

20 JUDGE VANASKIE: You certainly may.

21 MS. GOLDENBERG: I'll keep it short. What I've heard
22 as to every topic that we've raised today is that Aurobindo
23 needs more time, that they're considering things, and, you
24 know, we did actually offer two different times yesterday to
25 speak with Ms. Heinz but got no response whatsoever, and it is

1 frustrating that we get to these case management conferences
2 and we hear over and over again that things are being
3 considered, they would like to meet and confer, that this all
4 just appears to be a delay process, and we're going to have to
5 keep leaving depositions open if we don't get these issues
6 resolved.

7 JUDGE VANASKIE: Yes, I understand that, and as I
8 said, this is frustrating to be listening to this and it does
9 seem that we're -- I've heard it recently expressed as death
10 by meet and confer. So I want this process to go forward.

11 Go ahead, Ms. Heinz.

12 MS. HEINZ: I am sorry to interrupt.

13 JUDGE VANASKIE: No, that's all right.

14 MS. HEINZ: This is a letter that I just received --
15 I'm sorry, go ahead, Your Honor.

16 JUDGE VANASKIE: Go ahead. You proceed, I'm sorry.

17 MS. HEINZ: Thank you. This is a letter that we
18 received Friday night after a six-hour deposition that day,
19 that plaintiffs proceeded with, it was a fact witness, and
20 then the one scheduled for tomorrow is another fact witness
21 and Ms. Marlene is correct, we don't have a 30(b)(6) witness
22 scheduled until -- I believe it's the third week in March --
23 I'm sorry, April, but this is a letter that I just received
24 Friday night, and as Your Honor can see, they've identified a
25 lot of documents here, you know, and we are not conceding that

1 they're right about anything, but this is a lot to go back and
2 review, and we're willing to do that and work through that
3 with them, but to send me a letter Friday night and expect me
4 to turn it around, you know, when I'm dealing with -- with
5 clients that are in India as well, is just, it's unreasonable,
6 and I would appreciate, you know, like I offered to meet with
7 them later this week or early next week, once we have a chance
8 to digest all this and get back to them on it.

9 JUDGE VANASKIE: All right. I greatly appreciate
10 that explanation, and you're right, that's a brief period of
11 time from Friday night until now to have expected to have had
12 an opportunity to make your client's position with respect to
13 this host of documents that are listed at Pages 16 through 18
14 of the plaintiffs' letter.

15 I want you to have a meaningful meet and confer, I
16 expect to get an update on this in writing by next Tuesday. I
17 know that's only six days away, but I want to know where
18 things stand and we'll address it again next Wednesday.

19 Now, there was one other item in the plaintiffs'
20 letter, and that dealt with a list of 42 documents withheld on
21 the basis of draft and other products.

22 Did you want to address that, Ms. Goldenberg?

23 MS. GOLDENBERG: Yes, Your Honor. This again is a
24 summary of documents that was sent to Ms. Heinz awhile ago.
25 So this is not something that she received last week, even

1 though I'll note that Aurobindo's privilege log is less than
2 200 documents, so I don't think that was too big of an ask.

3 But this is 45 documents and a number of these, I'll
4 note, I think there's at least four on the spreadsheet that
5 relates to Mr. Gorijavolu who again is being deposed tomorrow,
6 and these are -- these have been withheld by Aurobindo and
7 we've identified these through searches within our system, but
8 if you look at the spreadsheet, all clearly appear to be
9 relevant to this case. I mean, we see things titled Valsartan
10 statement.doc. You know, Valsartan virgin drug recall letter
11 two times in this log. EPI testing proposals, Aurobindo.pdf
12 with additional Valsartan information in there.

13 So I mean, we just can't understand why these have
14 been withheld and on these, I'm not really sure why additional
15 meet and confers would be helpful. I think that Aurobindo
16 just needs to produce them.

17 JUDGE VANASKIE: All right. Ms. Heinz?

18 MS. HEINZ: Your Honor, there was a ruling early on
19 in the litigation when we were going back and forth among the
20 parties with the Court on the plaintiffs' request for
21 production, and I recall there being a ruling that the
22 defendants did not have to produce draft documents.

23 Now, with that being said, I did tell Ms. Goldenberg
24 that we're going to go through every single document and
25 re-review those that are on her list. It's my understanding

1 that my colleagues are almost complete, if not already
2 complete with that process, and we just -- we're going to be
3 discussing with our clients and we should hopefully be able to
4 reach an agreement with the plaintiffs' counsel on, you know,
5 some additional documents that I think we're going to be able
6 to agree to produce.

7 But again, you know, there's a lot going on here, and
8 we're trying to get through it all. We're not refusing to go
9 through this meet-and-confer process with the plaintiffs. We
10 are trying to evaluate everything so that we can -- that we
11 produce everything that is responsive prior to these
12 depositions.

13 MS. GOLDENBERG: Your Honor, if I could.

14 JUDGE VANASKIE: Yeah, go ahead, Ms. Goldenberg.

15 MS. GOLDENBERG: The draft document ruling that
16 Ms. Heinz is referring to, I assume what she's talking about
17 is the discussion that we all had about third-party subpoenas
18 and the -- I don't have the hearing transcript date in front
19 of me, but I can tell you I have read it fairly recently and
20 that ruling was made by JUDGE VANASKIE only as to third-party
21 recall vendors.

22 It has nothing to do with draft documents for the
23 manufacturers, and I think it's notable that no other
24 manufacturer, to my knowledge, has been holding documents back
25 on this basis. Every other defendant has produced draft

1 documents and I'm not really sure why Aurobindo is choosing to
2 interpret a ruling in that way.

3 But to the extent Your Honor is considering asking us
4 to have -- further about these documents, I would just ask
5 that at a minimum, the documents relating to Prasad Gorijavolu
6 which is entries Line 6, 7, and 35 on our spreadsheet be
7 produced today, so that at least we have the benefit of those
8 for tomorrow.

9 JUDGE VANASKIE: Ms. Heinz?

10 MS. HEINZ: Yes, thank you, Your Honor. The ruling
11 I'm referring to was not the one that Ms. Goldenberg
12 mentioned. I don't recall when exactly it was, off the top of
13 my head. I'm happy to pull that information and send it to
14 Your Honor, if you would like, but -- and I can certainly
15 provide an update if we're not able to reach, you know, work
16 out this dispute before the CMC next week, but I do recall,
17 and I'll let the other manufacturers speak for themselves, but
18 I do recall there being a ruling when we were finalizing the
19 plaintiffs' Rule 34 request for production, I believe it was
20 in 2019, that the parties do not have to produce draft
21 documents.

22 JUDGE VANASKIE: Now, Ms. Goldenberg just identified
23 by -- I guess by row or line number three particular
24 documents. Did you say 6, 7, and 35, Ms. Goldenberg?

25 MS. GOLDENBERG: Yes, Your Honor, and those are the

1 three where the custodian is Prasad Gorijavolu.

2 JUDGE VANASKIE: Well, I'm going to order that they
3 be produced so that the deposition can proceed.

4 MS. HEINZ: And, Your Honor --

5 JUDGE VANASKIE: Go ahead.

6 MS. HEINZ: We actually -- I think that we are
7 willing to produce those. We don't need an order to produce
8 those.

9 JUDGE VANASKIE: Okay. Good. Great.

10 MS. HEINZ: That's fine with us.

11 JUDGE VANASKIE: So they'll be produced. You can
12 send me the order that you are referring to, Judge Schneider's
13 order with respect to these other documents, but let's get
14 this deposition moving forward. Great.

15 All right. Anything else on Aurobindo,
16 Ms. Goldenberg?

17 MS. GOLDENBERG: Now in our agenda letter, Your
18 Honor. If you want to do ToxRox and Meridan now, I'm happy to
19 do that. Otherwise, we can save it to the end.

20 JUDGE VANASKIE: Are you prepared to talk about
21 ToxRox and Meridan, Ms. Heinz?

22 MS. HEINZ: Your Honor, my colleague, Ethan Feldman
23 is on the line and he's going to address that.

24 JUDGE VANASKIE: All right. Well, let's address that
25 right now. All right. Here's the problem I'm having, having

1 read the submissions concerning the subpoenas to ToxRox and
2 Meridan.

3 How am I -- what's my basis for determining whether
4 the documents were prepared primarily in anticipation of
5 litigation as opposed to for business purposes?

6 And I'm going to ask that question first of you,
7 Ms. Goldenberg. How am I to make that determination?

8 MS. GOLDENBERG: Your Honor, my understanding of the
9 role that these two companies played was that they had nothing
10 to do with litigation. These companies were hired by
11 Aurobindo so that they could help Aurobindo respond to the FDA
12 483 letters, and I believe that Ms. Heinz actually dropped a
13 footnote in her brief when we originally briefed this issue,
14 indicating that her firm wasn't even in the picture at the
15 time these two entities were hired. And so I think the
16 easiest way to draw that line is, that's not why these
17 companies are here.

18 JUDGE VANASKIE: All right. Mr. Feldman?

19 MR. FELDMAN: Yes, Your Honor. I would just like to
20 point out that at the time the law firm of Hogan and Lovells
21 was retained by Aurobindo, and with regard to preparation in
22 anticipation of litigation, I mean, you know, Aurobindo
23 received this SBA warning letter, you know, and it's
24 reasonable to believe that after receiving a warning letter
25 that future regulatory compliance is on the horizon.

1 You know, I don't think it would be reasonable to
2 think that the FDA would just issue a warning letter and that
3 would be the end of it. So as far as -- in that regard, you
4 know, future regulatory compliance was contemplated in the
5 *Todd V STAAR Surgical* case, and it was found that the
6 consultant's documents were protected by work product.

7 JUDGE VANASKIE: So you're relying solely on that
8 case, is that it?

9 MR. FELDMAN: Yes, Your Honor.

10 MS. GOLDENBERG: Your Honor, I'll just point out that
11 when this issue was originally raised by Aurobindo in the
12 context of the third-party subpoena hearing, JUDGE VANASKIE
13 specifically pointed to his *In Re Riddell* Concussion Reduction
14 litigation decision, and notably, in that case, you know, he
15 said, it is true that many of *Riddell's* documents were
16 prepared because of Congressional inquiries into concussions,
17 however, no evidence exists to show this was likely to lead to
18 a litigation, and that is directly analogous to the situation
19 here.

20 Just because the FDA inspects your facility and
21 issues a warning letter, that doesn't mean automatically that
22 there's going to be litigation.

23 These facilities, as a precursor to being -- as a
24 prerequisite to being able to sell drugs in the United States
25 submit themselves to investigations by the Food & Drug

1 Administration. These are conducted regularly, and that's
2 just part and parcel of being a manufacturer of a drug that's
3 sold in the United States to United States consumers.

4 JUDGE VANASKIE: All right. Anything else,
5 Mr. Feldman?

6 MR. FELDMAN: Yeah, I believe most of the documents
7 at issue in Riddell had to deal with the public relations firm
8 and I think that, you know, consultants hired with respect to
9 FDA compliance, it's a little bit different than that, so
10 that's all I would like to point out.

11 JUDGE VANASKIE: Well, I have the subpoena addressed
12 to ToxRox in front of me, and some of these documents, I don't
13 see how they could -- are you seeking to quash the entire
14 production? But some of these documents wouldn't seem to be
15 covered by work product protection. I mean, to go through
16 each category of documents that are sought and identify what
17 might be covered by work product and what wouldn't be.

18 MS. GOLDENBERG: Your Honor, we actually have an
19 agreement with Aurobindo that they were going to produce
20 documents, and so the only issue that we need you to rule on
21 today is whether the documents on their privilege log are
22 actually protected by privilege or work product doctrine.

23 JUDGE VANASKIE: Thank you very much for that.

24 All right. Well, that clarified the matter for me,
25 and I'll take a look at those particular items that are listed

1 on that log for purposes of making a determination to the
2 extent that I can, that the documents would not have been
3 prepared primarily for -- in anticipation of litigation. I
4 think that's the key question, and I'm somewhat familiar with
5 this issue more recently doing work in the data breach context
6 for consultants. Reports have been found not to have been
7 prepared in anticipation of litigation, and in those instances
8 that I have in mind, there usually was some preexisting
9 relationship between the consultant and the party that would
10 suggest a business purpose for them.

11 So I have to take a careful look at this, I
12 understand, but I will get you a prompt ruling with respect to
13 that matter. We don't need to address it any further right
14 now.

15 MS. GOLDENBERG: Appreciate it. Thank you, Your
16 Honor.

17 JUDGE VANASKIE: All right. Thank you.

18 MR. FELDMAN: Thank you, Your Honor.

19 JUDGE VANASKIE: Anything else on Aurobindo?

20 MS. GOLDENBERG: Just to circle back to the first
21 issue, Your Honor, because I wasn't clear on whether or not
22 there was a ruling as to the noncustodial documents.

23 Can you just let the parties know where you ended up
24 on that, so that we can make sure that we move forward in
25 compliance with your guidance?

1 JUDGE VANASKIE: Now again, I'm going to go back to
2 you then with the question by -- what is encompassed by
3 noncustodial documents? Are those the shared drives as well
4 as the third-party programs that are mentioned?

5 MS. GOLDENBERG: They are both of those things, Your
6 Honor, and any other shared drives that I don't know about
7 yet, but that have responsive information to our request for
8 production.

9 JUDGE VANASKIE: Ms. Heinz, correct me if I'm wrong
10 on this, but my understanding is that you will be going back
11 to your client to ascertain whether those shared -- as to the
12 shared drives and to those programs, call them programs, that
13 are mentioned in the letter, things like Oracle have been
14 searched; is that correct, that you're going back to verify
15 that?

16 MS. HEINZ: Correct, Your Honor.

17 JUDGE VANASKIE: Yeah, I don't think I meant to issue
18 any order or ruling with respect to that, Ms. Goldenberg. I
19 thought it was going to be a matter that you all were going to
20 continue to address and that I'll get a status report next
21 Tuesday. That will be included in the status report next
22 Tuesday.

23 MS. GOLDENBERG: Got it. Thanks, Your Honor.

24 JUDGE VANASKIE: Okay. Thanks. All right. Now
25 we're up to Mylan.

1 MR. DAVIS: Your Honor, this is John Davis for the
2 plaintiff.

3 JUDGE VANASKIE: Okay.

4 MR. DAVIS: I think it makes sense to handle this one
5 discrete issue regarding Unit 7 in conjunction with the review
6 of the 4,000 documents, because this is one of the areas of
7 Mylan's withholding as nonresponsive documents that we think
8 are highly relevant.

9 So I think, you know, the two sort of complement each
10 other and probably should be handled together, but if Your
11 Honor's willing, I'll start with Unit 7.

12 JUDGE VANASKIE: Yeah, I interrupted, but I agree
13 they should be handled together. Go ahead.

14 MR. DAVIS: Sure. So Unit 7 -- and let me just give
15 you a little background on Unit 7. Unit 7 is an API
16 manufacturing facility in India. It's operated by Mylan Labs
17 Limited, which also operates the other Indian facilities at
18 issue in this case, namely, Unit 8, for example, which is the
19 API manufacturing facility that manufactured Valsartan API for
20 the U.S. market.

21 It does manufacture other sartans, we've learned,
22 including Irbesartan. The same Mylan Labs Limited leadership
23 oversees both Unit 7 and Unit 8, including, for example,
24 Dr. Anthony Gomes, whose deposition we've had to postpone. It
25 was supposed to be yesterday, but we've had to postpone due to

1 certain document production deficiencies we've identified for
2 Mylan and Mylan is, for the most part, is going to be
3 producing documents, but it forced a slight delay in that
4 deposition.

5 Dr. Gomes is the global head of generic -- or sorry,
6 global head of API quality. It has oversight of Unit 7 and
7 Unit 8.

8 Unit 7 used ortho-xylene manufactured by Vega Life
9 Sciences. Ortho-xylene has been identified by Mylan in its
10 root cause investigation as being the primary culprit for
11 introducing nitrosamine contamination into the Valsartan API
12 recovered o-xylene or ortho-xylene. Vega is a recovered
13 solvent manufacturer that Mylan used for that ortho-xylene
14 recovery, both in Unit 7 and Unit 8, and the FDA inspected
15 Unit 7 in February 2020 and issued a very recent establishment
16 inspection report in September 2020, an EIR, that found, you
17 know, a number of serious deficiencies, and, you know, the
18 letter laid out two of them that are, in my opinion, highly
19 relevant to this case.

20 One that is in 2020, you know, we're talking almost
21 two years after Mylan's discovery of its nitrosamine
22 contamination issue and, you know, supposed implementation of
23 corrective actions related to that, that Mylan was not testing
24 its recovered o-xylene for impurities in 2020 at Unit 7.

25 And furthermore, that Mylan was not adequately

1 vetting its recovered solvent vendors, and Vega is the primary
2 example there. There's a lot of discussion in that EIR, the
3 FDA issued to Mylan regarding Vega, and for example, an audit
4 that Mylan itself conducted of Vega, which I believe Mylan has
5 said they're willing to produce to us, but had not been
6 produced before.

7 So, you know, just those two observations are highly
8 relevant to this case, because our, you know, one of the
9 things we're establishing in depositions with Mylan, is that
10 Mylan never tested its recovered ortho-xylene, not only in
11 2020, but at any point before that. And it's particularly
12 baffling that they're still not doing it in 2020, but that's
13 neither here nor there for now, but, you know, Mylan gave a
14 set of responses to the initial observations, what's called a
15 483.

16 Mylan's initial responses to that 483 said, hey,
17 don't worry about this, you know, we've implemented some
18 corrective actions at Unit 8 as a result of our learning from
19 the Valsartan contamination, and we're going to be applying
20 those here to Unit 7.

21 And so not only, you know, is -- so Mylan is
22 basically telling the FDA, hey, look at what we did here at
23 Unit 8, but then they're telling us in this litigation that
24 it's not relevant.

25 So I think it's highly relevant. I spent about

1 probably an hour and a half questioning Mylan's witness,
2 30(b)(6) designee on it the other week, and that's without the
3 benefit of the documents we're asking for.

4 I had -- I believe I got the 483 observations from
5 FDA Villa, and the EIR was just, I suppose accidentally
6 produced by Mylan to us, but we don't have the benefit of any
7 of the other correspondence with the FDA, any of the other
8 documents generated as a result of that.

9 And so our request here for Unit 7 is not, you know,
10 at this point, to have Mylan go back and reintroduce search
11 terms. Actually, I probably think that our previous search
12 terms would cover a lot of these documents anyways, they were
13 just withheld in the review process is my understanding, but I
14 think the Court should order Mylan to produce these and to
15 produce them posthaste, because we do have a lot of
16 depositions coming up.

17 We've had to postpone the third day of Mr. Glover, as
18 well as Dr. Gomes to resolve some of the document issues that
19 we discovered and to have this Unit 7 issue resolved as well.

20 So I'll start with that and then if Your Honor has
21 any questions on the 4,000-ish documents, I'm happy to address
22 those as well.

23 JUDGE VANASKIE: Well, we'll come back to that. Who
24 will be addressing this on behalf of Mylan?

25 MR. TRISCHLER: Your Honor, this is Clem Trischler.

1 Good afternoon.

2 JUDGE VANASKIE: Good afternoon, Mr. Trischler.

3 MR. TRISCHLER: There's a great deal too on the line
4 to Mr. Davis's statements to the Court, but let me start with
5 this. I took note of the Court's stated concern at the outset
6 of this hearing about the frustration over the continued
7 discovery induced. Indeed, the Court has expressed that
8 frustration multiple times during this hearing, and on behalf
9 of Mylan and I suspect all the defendants, I echo that concern
10 and frustration, and in this case it particularly stems from
11 the fact that all of this -- of all of these issues that are
12 now being raised with respect to Mylan relate to an attempt by
13 the plaintiff to set aside a core discovery ruling that was
14 entered by JUDGE VANASKIE well over a year ago.

15 And so what we are doing here now, and when we wonder
16 why we are continuing to argue discovery issues, what we are
17 doing here now is, you know, a clever attempt by the
18 plaintiffs to set aside a ruling from the Court in which the
19 Court was clear that the scope of discovery in this -- in this
20 litigation, will be on the facilities that were involved in
21 producing the API and in producing the finished dose products.

22 Unit 7 is a separate plant operated by Mylan that is
23 250 miles away from Unit 8 where the Valsartan API was
24 produced. Valsartan API was never produced at Unit 7.

25 Finished dose Valsartan products were never produced

1 at Unit 7. Mr. Davis mentioned that while some sartans were
2 produced at Unit 7, well, none of Mylan's other sartan
3 products are at issue in this litigation. Mylan is not named
4 in the master complaints involving Irbesartan and Losartan.
5 There were no recalls of Mylan's other sartan products. There
6 were no recalls of any products at Unit 7. Unit 7 has nothing
7 to do with this case.

8 JUDGE VANASKIE made that determination over a year
9 ago, and it is somewhat frustrating that we continue to argue
10 discovery matters particularly in cases where Mylan has
11 produced over -- well over a million pages of documents in
12 this litigation collectively and my client's productions are
13 representative of that of the other defendants. I can safely
14 say to the Court that five to ten million pages of documents
15 have been produced in this litigation, and now we're arguing
16 about whether or not we need to open the door a little further
17 and go down the slippery slope of revisiting a core discovery
18 ruling.

19 I don't think there's -- there's absolutely no basis
20 for it. And we argued this in front of Your Honor, I think a
21 couple of weeks ago, Mr. Honik and I had a discussion in front
22 of the Court on it. There's no basis to expand discovery to
23 other facilities that were not involved in the production of
24 this product. Mr. Davis made the suggestion that Mylan's not
25 testing recovered solvent. That's absolutely untrue. Mylan

1 may not be conducting tests that the plaintiffs want to ask
2 the facts suggest it necessary, but Mylan tested recovered
3 solvent pursuant to requirements established by the FDA at the
4 time the recovered solvents were being used in Valsartan.
5 Mylan tested the recovered solvents pursuant to its --
6 pursuant to specifications and consistent with industry
7 practices. The fact that they don't like the tests or that
8 they now want to argue that the tests are -- additional tests
9 were required, that, you know, that may be their argument, but
10 to suggest to the Court that no testing was done, that's
11 simply not true.

12 I would ask this Court, if we ever want to bring an
13 end to the discovery battles in this case, I would ask that
14 the Court maintain that the core discovery rulings apply to
15 this case and that the plaintiffs can't revisit them at each
16 and every opportunity, and if that's the case, then the
17 plaintiffs' motion to expand discovery to Unit 7 should be
18 denied, because it will be a very slippery slope, Your Honor.

19 When we talked about this two weeks ago, Mr. Honik
20 told the Court, well, we just want the regulatory
21 communications, we just want the EIR, we just want the 483, we
22 just want Mylan's response to the warning letter.

23 Today, I hear Mr. Davis tell you something completely
24 different, that Mylan should now run search terms against all
25 the Unit 7 custodians and try and find out what other

1 documents that there might be relevant.

2 And we will be here two years from now arguing the
3 same thing, and then when witnesses are deposed, they'll be
4 subject to requests for second and third depositions. It has
5 to come to an end and it won't come to an end if we're not
6 going to pay heed to discovery rulings that were made over 15
7 months ago.

8 JUDGE VANASKIE: All right. Thank you.

9 MR. DAVIS: Your Honor, may I respond?

10 JUDGE VANASKIE: Yes, I'd like your response.

11 MR. DAVIS: Thank you. Just a few points. Again,
12 this is John Davis for the record.

13 First of all, JUDGE VANASKIE, when he entered the
14 macro discovery order, he explicitly said on the record that
15 with good cause, it could and should be revisited. That was
16 entered a long time ago, long before a lot of the issues in
17 case were fully elucidated.

18 So it is proper for us to go back and revisit it,
19 particularly where -- it's here, what the FDA is telling
20 Mylan, they're doing wrong, that Unit 7 directly bears on what
21 we allege. They were doing wrong long before the Valsartan
22 recall.

23 And, you know, Mr. Trischler brought up, you know,
24 that the plaintiffs -- you know, and this is, granted, I
25 believe, a factual dispute that a jury will want to resolve

1 eventually, but it's not plaintiff saying that Mylan wasn't
2 testing its recovered solvent, it's the FDA who was saying
3 that, and that's why these regulatory communications are
4 highly relevant, because not only -- it provides insight into,
5 you know, the FDA's position, which -- and position for a long
6 time about what's required in terms of testing, and what's
7 required in terms of validating your use of recovered solvent.
8 And those communications between Mylan and the FDA regarding
9 Unit 7 are highly relevant for that very reason.

10 I mean, this is an emerging fact dispute even on this
11 call today, as to what's proper testing and not testing. And
12 given the FDA's, you know, thoughts on that as written to
13 Mylan and getting Mylan's responses to that as to Unit 7 bear
14 directly on, you know, what the FDA has been telling Mylan at
15 Unit 8. And same thing for, you know, Mylan telling the FDA
16 that it, you know, what it's doing in Unit 7 in response was
17 based on learning Unit 8.

18 Finally, one point of clarification is, I'm not
19 asking for search terms at this point, that's not what I said.
20 I accepted, you know, that I wanted the communications, the --
21 nothing's changed between what, you know, Mr. Honik brought up
22 the last time and what I'm asking for today. I said at this
23 point, I'm not asking for search terms. So I just wanted to
24 clarify that for the record.

25 MR. TRISCHLER: Your Honor -- sorry, John. And, Your

1 Honor, the key point that -- what I heard Mr. Davis say is "at
2 this point." That's the slippery slope, that's the crack in
3 the door that I'm talking about. That's why discovery never
4 comes to an end, and keep in mind, the timeline. This is a
5 2020 inspection done in a facility that never made Valsartan.
6 And whatever comments FDA may have made two years after these
7 recalls concerning inspection procedures at a facility that
8 never made a drug, that any plaintiff in this case took, has
9 no bearing, no relevance, which is the touchstone for
10 discovery, to what Mylan should have done in 2018. Has none.

11 MR. HONIK: Your Honor, this is Ruben Honik. May I
12 be permitted to briefly underscore a part of this argument?

13 JUDGE VANASKIE: Yes, Mr. Honik, briefly.

14 MR HONIK: I will be very brief, Your Honor. 15
15 months ago JUDGE VANASKIE would have had no ability to know
16 that the problem and the root cause for Mylan's contamination
17 of its drug had to do not with the direct chemical process,
18 but with the manner in which they used recovered solvent.

19 That was unknowable, and Mr. Davis is correct, that
20 for good cause, if you show a relationship or relevancy, of
21 course JUDGE VANASKIE would be entertaining our request today
22 just as you should.

23 The plain fact is, that the problem, the root cause,
24 as identified by the FDA and not denied by Mylan, was this
25 recovered solvent use, which was used in both Unit 7 and

1 Unit 8.

2 And both of the inspections undertaken by the FDA
3 specifically zero in on that, and Mylan, not anyone else, but
4 Mylan specifically referred to its operation at Unit 8 and the
5 recovered solvent in addressing the 483 concerns raised about
6 Unit 7. There is a direct linkage, and this idea that we
7 should fear a slippery slope in the face of obviously relevant
8 information, the only information we've sought thus far,
9 should not worry the Court, because it is so directly on point
10 to what we need to discover in this case.

11 That's the only thing I wanted to emphasize.

12 JUDGE VANASKIE: If you want to respond, you can.

13 MR. TRISCHLER: I need to, thank you. And with all
14 due with respect, what Mr. Honik just said to the Court is
15 absolutely wrong. I'm looking at a transcript from the
16 hearing on the -- what preceded the entry of the macro
17 discovery orders, and my colleague, Jason Reefer was speaking
18 to the Court and Mr. Reefer told the Court, this was before
19 the macro discovery orders were entered, quote: Judge, I'm
20 not a process chemist, but the short story is that Mylan has
21 shown that the impurity was the result of -- I'm sorry, we
22 used some solvent with respect to a very, very specific sort
23 of chemical pathway that occurs in the two steps of the API
24 manufacturing process, end quote.

25 And then there goes on to be a further discussion on

1 the record prior to the entry of the macro discovery order.
2 The Court was told, the plaintiffs were told, what Mylan's
3 root cause analysis was.

4 And so to suggest that the Court made this ruling in
5 a vacuum without any knowledge, this revisionist history of
6 the highest order.

7 MR HONIK: Your Honor, this proves my point exactly.
8 JUDGE VANASKIE had no idea that that same recovered solvent
9 root cause issue was present anywhere but Unit 8. It now
10 comes to light that it was the identical problem in Unit 7
11 with other sartans and that Mylan of its own accord in
12 addressing the concerns of FDA lumped the two units' use of
13 recovered solvent together.

14 This is a shell game being played by Mylan so that we
15 can't see the substance of their material responses to the FDA
16 concerning the very same problem present in Unit 7 that was
17 present in Unit 8.

18 There was no way for JUDGE VANASKIE to know that.
19 There was no way for JUDGE VANASKIE to know that the solvent
20 issue was present at any facility, other than the single
21 facility where the Valsartan was made.

22 But we now know differently. We now know that the
23 FDA uncovered that the root cause of the problem was present
24 at two of their units, and we are predictably trying to seek
25 discovery about it.

1 JUDGE VANASKIE: All right. This is an important
2 issue, obviously. I am very much concerned about this
3 slippery slope and about expansion of discovery that may have
4 marginal relevance here. I'm not in a position right now to
5 -- I want to issue a written ruling on this so that my
6 reasoning is clear in terms of which way I go on this. You've
7 given me, both sides, great argument.

8 So what I'll do is, promptly issue a written ruling
9 on whether this discovery with respect to Unit 7 should go
10 forward. If there is any discovery that goes forward, it
11 would be limited to regulatory communications, but I'll issue
12 a written decision on that.

13 Now, I did want to transition, if we could -- and
14 Karen, are you all right to continue?

15 THE COURT REPORTER: Yes, Judge, I'm fine.

16 JUDGE VANASKIE: Okay. On the documents withheld as
17 nonresponsive. Now, you were kind enough to send to me 12
18 documents that have been withheld as nonresponsive that were
19 specifically flagged by plaintiffs.

20 And I've looked at those documents and I'm having a
21 hard time understanding why they would be nonresponsive. I'm
22 looking at a document now that's called Deviation
23 Investigation Report, dated September 9, 2016, dealing with
24 Unit 8, and the matter of residual solvents, and maybe this is
25 my lack of familiarity in the matter, and then it makes it

1 more difficult, residual solvents for Valsartan VS22 batches.
2 And we're not meeting the specifications with respect to
3 o-xylene content after 12 hours.

4 Now, I'm not a chemist. I was pretty good in
5 chemistry, but I wasn't -- I'm not a chemist, and so looking
6 at this, how could I determine whether it's responsive or not?

7 MR. DAVIS: I think our argument here from - if you
8 want to hear from me, John Davis, I think that's highly
9 relevant, Your Honor. Residual solvent testing is the testing
10 we're interested in for API. This is Unit 8, it's Valsartan.
11 It's Valsartan for the U.S. market using the VST code.

12 It's o-xylene. I mean, this has all the hallmarks of
13 being highly relevant. Obviously, I haven't seen the
14 document, but, Your Honor, I would encourage you to order
15 Mylan to produce it, because when something is questionably
16 responsive or not responsive, it should be produced. And that
17 is by both sides in the adversarial nature of the proceedings
18 that we have. But to me, I don't even think this is
19 questionable. I think that's a highly relevant document.
20 Thank you.

21 JUDGE VANASKIE: All right. Are you ready to address
22 this, Mr. Trischler?

23 MR. TRISCHLER: Sure, Your Honor. And my apologies,
24 I'm at a bit of a disadvantage at the moment, because unless
25 -- unless I was mistaken, I did not see this issue on the

1 agenda, so I don't have the document or the 12 documents in
2 front of me, so I'm not -- I'm not prepared to make -- I'm not
3 a chemist nor did I do very well in chemistry, so I'm not
4 prepared to answer the Court's direct question about those 12
5 documents.

6 My recollection from our last hearing was, we
7 submitted those 12 documents to Your Honor along with a list
8 of the other withheld documents, because you may recall that
9 the issue was, you know, as part of the discovery agreements
10 and orders, the defendants were permitted to withhold
11 nonresponsive attachments to otherwise responsive documents,
12 and these 4,000 or so documents fell within that category, and
13 the Court was going to request a random sampling of those
14 documents.

15 So I did not do anything to prepare for this issue or
16 to -- and would not be able to frankly, intelligently respond
17 to your question about this particular document at the moment,
18 because I perhaps wrongly assumed that we were waiting for
19 further direction from the Court as to what was going to take
20 place with respect to this issue.

21 JUDGE VANASKIE: No, I think your assumption was
22 reasonable, Mr. Trischler, and we'll give you the opportunity
23 to prepare adequately, and we'll discuss it at our conference
24 call next Wednesday.

25 But I would urge that you take a look at these 12

1 specific documents and be prepared to tell me why they're not
2 responsive, because I'm having a difficult time making that --
3 based on the face of it, I find them to be responsive. So you
4 understand where I'm coming from.

5 MR. TRISCHLER: I do, Your Honor.

6 JUDGE VANASKIE: Okay.

7 MR. DAVIS: Your Honor, this is John Davis. I feel
8 like I need to put on the record my concern about, you know,
9 these seem like highly relevant documents and we have
10 depositions that are going forward imminently. We've got, for
11 example, next week, I'm taking the deposition of Dr. Daniel
12 Snyder who is designated on Mylan's root cause investigation,
13 as well as risk assessment topics, and, you know, even that
14 document that Your Honor referred to, is the document that I
15 sure would like to have in my hand when taking that
16 deposition.

17 So I have some --

18 JUDGE VANASKIE: What day is the deposition?

19 MR. DAVIS: March 31st, I think next Wednesday
20 actually, so I won't even be on the CMC, and I doubt
21 Mr. Trischler will be either. He probably will be attending
22 that deposition.

23 JUDGE VANASKIE: All right.

24 MR. TRISCHLER: Well, that was certainly the plan,
25 but in light of the fact that the CMC was just rescheduled

1 today. But I can have somebody on the call with the Court to
2 address this issue, Your Honor, while John and I are in the
3 deposition.

4 JUDGE VANASKIE: Well, Mr. Trischler, would you be in
5 a position to give me by Monday of next week a written
6 statement as to why -- just as to these 12 documents, why they
7 are not responsive, and -- because if I find that they are
8 responsive, at least as to the 12 documents, a determination
9 could be made to require their production. Obviously they
10 exist, can be easily produced, so that they are available for
11 the deposition. Would you be able to do that?

12 MR. TRISCHLER: Sure.

13 JUDGE VANASKIE: Okay. So I'll ask by Monday of next
14 week I get a written statement of position from Mylan with
15 respect to these 12 particular documents as to why they're not
16 responsive.

17 All right. I think that covers the issues involving
18 Mylan. Is there anything else? Okay.

19 MR. DAVIS: Your Honor, just for one question of
20 clarification. I note, and I believe I might have missed this
21 at the outset when Your Honor brought this up, but I just
22 wanted to see where we were on -- and if there's anything
23 plaintiffs' side can do in terms of the random sampling. I
24 believe that Your Honor had mentioned the last time.

25 JUDGE VANASKIE: All right. Here's what I -- I'm

1 glad you brought it up because I needed to circle back to
2 that, because I did want to cover that.

3 I've determined and I want to find out if anybody
4 disagrees, that a sample size of 352 documents out of those
5 4,198 documents would be statistically significant. It would
6 have a margin of error of plus or minus 5 percent and then
7 95 percent confidence level.

8 I've used a random number generator, and I will send
9 out via e-mail the number -- the rows, the numbered rows, that
10 documents should be produced to me for in-camera review, and
11 I'm hopeful that can be done promptly.

12 As I said, it's 352 documents. Unless, and I'll ask
13 this first of you, Mr. Davis, do you think the sample size is
14 too small?

15 MR. DAVIS: I personally don't have any issue with
16 that. I think that should be sufficient for our purposes.

17 JUDGE VANASKIE: And, Mr. Trischler, is that a
18 problem from the defense perspective?

19 MR. TRISCHLER: Your Honor, my phone cut out when you
20 stated the number, but I'm willing to accept whatever,
21 whatever number you propose.

22 JUDGE VANASKIE: Yeah, it's 352.

23 MR. TRISCHLER: Thank you.

24 JUDGE VANASKIE: And we'll e-mail to you the row
25 numbers for the documents that should produced for in-camera

1 review. I'm assuming, and that's not always a good thing to
2 do, that they can all be produced to me electronically.

3 MR. TRISCHLER: I believe that should be doable.

4 JUDGE VANASKIE: All right. Okay. And then I'll
5 undertake my review for purposes of determining
6 responsiveness. But I'm not committing to have that completed
7 by next Wednesday. All right? But hopefully, it won't take
8 too long.

9 Anything else on that, Mr. Davis?

10 MR. DAVIS: Nothing here, Your Honor. Thank you.

11 JUDGE VANASKIE: All right. And anything else on
12 your end, Mr. Trischler, on Mylan discovery?

13 MR. TRISCHLER: No, Your Honor.

14 JUDGE VANASKIE: Okay. Now, going again, I'm back on
15 plaintiffs' letter at Page 20. The next thing on the agenda
16 is defense request for dismissal of Louisiana plaintiff
17 claims, and I take it that's an issue for Judge Kugler. Is my
18 understanding correct?

19 MR. SLATER: Yes, Your Honor, this is Adam Slater.
20 We agree, this is a Judge Kugler issue.

21 JUDGE VANASKIE: Okay.

22 MR. GOLDBERG: Yes, Your Honor, that's correct.

23 JUDGE VANASKIE: Thanks, Mr. Goldberg.

24 The next issue was downstream defendants' obligations
25 regarding defendants' fact sheets.

1 MR. WILLIAMSON: Your Honor, this is George
2 Williamson for the plaintiffs. If I may provide some
3 background on this issue.

4 JUDGE VANASKIE: All right.

5 MR. WILLIAMSON: So the defense fact sheets were
6 negotiated over the course of many months, and plaintiffs had
7 requested that all of the defendants complete one fact sheet.
8 In other words, all of the information would be contained in
9 one fact sheet and served on the plaintiffs at one time.

10 The defendants insisted that they needed a staggered
11 fact sheet. So in other words, the pharmacy defendants would
12 have their own fact sheets, the wholesalers, the finished dose
13 manufacturers, and the API manufacturers all have their own
14 fact sheets, and there was also a lengthy timeline that was
15 put in place to allow the, you know, all four of the various
16 categories of defendants to complete a fact sheet.

17 So in other words, what happened is, pharmacy
18 defendants complete a fact sheet, they originally had 60 days,
19 I think it was extended to 90 days. Then the wholesalers
20 would take the information from the pharmacies, complete their
21 fact sheets, they have 60 days to do it. The finish dose
22 manufacturers then had 60 days and the API manufacturers had
23 60 days.

24 So at the conclusion of the defense fact sheet
25 process, we're talking about a period of nine months to

1 complete the fact sheet.

2 Now, that's what the defendants asked for and the
3 Court entered an order on August 6, entering these specific
4 fact sheets that each defendant would have to complete.

5 Now, the Court then said, plaintiffs, you select 20
6 cases for the defense fact sheet to be completed for. So in
7 other words, the defendants don't have to complete a fact
8 sheet for every single case filed in the MDL, only at least
9 originally for 20 cases, and the trigger date for the
10 beginning of those 20 cases, for the beginning of the fact
11 sheet was August 31st of last year, 2020.

12 JUDGE VANASKIE: Excuse me. I think I understand the
13 background here. So my question to you, are we dealing with
14 just four cases right now?

15 MR. WILLIAMSON: So in the immediate term, yes, we're
16 dealing with four cases. There's also an additional 18 cases
17 where this issue might be implicated.

18 Now, I will say we received an e-mail from the
19 wholesaler defendants at -- just the same time that we were
20 submitting our letter to the Court, and so we see now that the
21 wholesalers are interested in completing a fact sheet for
22 those four defendants -- excuse me, for those four bellwether
23 plaintiffs, but there's an additional 18th bellwether
24 plaintiff where this fact sheet process has just started, and
25 to the extent that there's an issue where a pharmacy has not

1 been named as a defendant in any of those 18 cases, we would
2 also ask that the wholesalers complete a fact sheet in those
3 cases.

4 Now, I can't tell you right now if that even exists,
5 but I suspect that it's probably not a very big issue and it
6 will not increase the number from four very much.

7 And so, you know, our request is that the wholesalers
8 complete fact sheets at least for the four, within seven days,
9 and then we'll continue to meet and confer with them to the
10 extent that there are -- that this issue pops up on the other
11 18, recognizing that we have sort of staggered the fact sheet
12 process for bellwether plaintiffs.

13 JUDGE VANASKIE: All right. Who will be addressing
14 this issue for the defendants?

15 MR. GEOPPINGER: Good afternoon, Your Honor, Jeff
16 Geoppinger, G-E-O-P-P-I-N-G-E-R, on behalf of the wholesaler
17 defendants.

18 JUDGE VANASKIE: Good afternoon.

19 MR. GEOPPINGER: Your Honor, as Mr. Williamson
20 alluded to it and as in our submissions, you know, we'd
21 like -- you know, we're agreeable to having some written
22 agreement to get these four cases done and be done with those.

23 We did -- you know, there are four cases where there
24 is no pharmacy fact sheet, so we didn't do one because the
25 defense fact sheet process. The order says, you know, we need

1 to do one when we get a pharmacy one identifying us, which is
2 what we did. Since there's no pharmacy in the case, there's
3 no fact sheet from the pharmacy, there's no way for us to do
4 it, at least according to the order.

5 But we'll take care of the four. The issue is the
6 other 18. And I'll take Ms. Winston's word for the numbers on
7 that, I don't have them off the top of my head. But, you
8 know, the four, as I understand from the plans, they have
9 depositions that we're going to try and get done on these
10 people and they want to expedite them and we'll do those,
11 we'll get them expedited as fast as we can. I don't know
12 about seven days, but, you know, we expedited the last fact
13 sheets we did, and we'll turn them around as quick as we can.

14 The one issue, though, of course, is that in these
15 four cases, all three wholesaler defendants are going to have
16 to, you know, review their records and produce a fact sheet,
17 right, and the other instance is, we had the pharmacy fact
18 sheet, they were targeted to -- the pharmacy told us who they
19 bought from and the wholesaler who was at issue, you know,
20 filled out a fact sheet.

21 Here, we're going to be going wider than that because
22 all three of us are going to have to do the work and respond
23 and say whether or not we're involved, and there's a thin
24 possibility given who the pharmacies are in these cases, none
25 of us are involved.

1 But with respect to the other 18, you know, I would,
2 you know, I'm not necessarily looking for a Court order, but
3 I'm asking, you know, for the plaintiffs to have some skin in
4 the game here. If this situation exists out there and there's
5 another plaintiff with a pharmacy that they have not filed a
6 lawsuit against, was not going to be doing a pharmacy fact
7 sheet, I think, you know, the plaintiffs should take the
8 opportunity to do a little discovery and do a little legwork
9 on that.

10 I don't understand if there's any time pressure with
11 those, and apparently, there may not be very many of them, but
12 to go out and find out, you know, hey, Mr., you know,
13 pharmacy, while we're getting the pharmacy records, can you
14 tell us where you got this stuff from? Was it one of these
15 wholesalers, was it somebody else.

16 And then once we have that information, they can come
17 back to the -- if it is indeed one of the three wholesalers
18 who are involved in the litigation, they can target their
19 request for a fact sheet to that wholesaler as opposed to
20 asking all three of us to put together a fact sheet, you know,
21 and likely two of us, at least two of us are probably going to
22 say, we don't have any information, if not all three of us.

23 JUDGE VANASKIE: Let's just resolve the issue as to
24 the four right now. And I'm hearing that there's an agreement
25 to produce those defense fact sheets for those four cases

1 where pharmacy -- pharmacies have not been identified as
2 defendants. Is that correct?

3 MR. WILLIAMSON: Yes, Your Honor, and if I may offer
4 -- I'm sorry, this is George Williamson again.

5 JUDGE VANASKIE: Thanks, Mr. Williamson.

6 MR. WILLIAMSON: If I may just offer that in this
7 situation where a wholesaler defendant does not -- has not
8 distributed a proper -- you know, a drug to a pharmacy that's
9 identified in a plaintiff fact sheet, I wouldn't think that
10 the wholesaler has an obligation to actually complete a fact
11 sheet. I think only the implicated wholesalers would
12 necessarily be required to complete a fact sheet.

13 So I don't think it's three for all four. Certainly,
14 the three wholesalers would have to check their records, but
15 if they didn't distribute the product, you know, I don't think
16 that they -- all three of them need to complete a fact sheet.

17 JUDGE VANASKIE: Well, that was my understanding,
18 Mr. Williamson, that -- well, Mr. Geoppinger was saying that
19 all three have to do the search. Did I understand that
20 correctly, Mr. Geoppinger?

21 MR. GEOPPINGER: Certainly, Your Honor. We will all
22 have -- all three will have to do the search, but we're
23 certainly -- back to your original question, yes, we agree to
24 do it for these four. We can, we can -- and we will all
25 search for the four, and if anybody comes up with data, we

1 will produce a fact sheet for that wholesaler. I guess we
2 will communicate otherwise when, you know, another wholesaler
3 looks and doesn't have anything. We can send an e-mail or
4 otherwise communicate to the plaintiff that the other two
5 wholesalers or -- maybe in one case all three wholesalers
6 don't have any information, but we're certainly happy to not
7 have to do three for every -- all -- the four plaintiffs and
8 can do it in that fashion.

9 And then I think all we have to figure out, Your
10 Honor, is the timeline. I know the plaintiffs have asked for
11 seven days. That seems quick to me. I guess a better way to
12 do it was, and again, I apologize, doing it off my head, but
13 perhaps Mr. Williamson does, about when these plaintiffs are
14 set to be deposed, and maybe we can come up with a timeframe
15 that works to make sure it's done in abeyance of that.

16 MR. WILLIAMSON: And, Your Honor, this is George
17 Williamson again. This sort of dovetails into one of our
18 other requests that the defense fact sheet be completed at all
19 levels prior to the plaintiffs' deposition, and so, you know,
20 we're asking for seven days because -- it's the information
21 that's contained in these fact sheets is critical preparing
22 our plaintiffs for deposition.

23 And so, you know, the information that we receive
24 from a wholesaler, for example, has information about, you
25 know, when recall notices were sent, you know, that's

1 extremely important for us, because we, you know, potentially
2 need to know on what dates the statute of limitations might
3 have been triggered. We need to be aware of these dates prior
4 to our client's deposition. I could go on and on with
5 other --

6 JUDGE VANASKIE: No need to go on and on. No need to
7 go on and on.

8 But you have four individual plaintiffs that are at
9 issue here. Are their depositions presently scheduled?

10 MR. WILLIAMSON: I believe that we have depositions
11 scheduled for all ten of the -- of the first -- of the first
12 set of bellwether plaintiff depositions.

13 JUDGE VANASKIE: When are those depositions scheduled
14 for?

15 MR. WILLIAMSON: So I can only give you the date for
16 my specific bellwether plaintiffs on the phone right now, Your
17 Honor, and I apologize. You know, I might have to get with
18 the defendants who might have a better idea of when each
19 bellwether plaintiff is scheduled for deposition. I can tell
20 you that my bellwether plaintiff is scheduled for deposition
21 on April 20th. I think there are some that are scheduled for
22 sooner than that, I think in the middle of April, I believe,
23 there are depositions set.

24 JUDGE VANASKIE: Well, I'm going to suggest that you
25 confer with Mr. Williamson to come up with a date by which

1 these defense fact sheets can be produced suitably in advance
2 of the scheduled depositions. It seems to me that's easily
3 done and should be able to be accomplished by assertions on
4 it. So I'll ask that you do that with the understanding as to
5 these four, they will be produced and we'll address questions
6 about others if and when they arise.

7 MR. WILLIAMSON: Okay. Thank you, Your Honor.

8 JUDGE VANASKIE: Thank you.

9 MS. JOHNSTON: Your Honor, this is Sarah Johnston on
10 behalf of the pharmacy defendants. I just wanted to ask for a
11 slight clarification on this issue, if I may.

12 JUDGE VANASKIE: Sure.

13 MS. JOHNSTON: So on Page 22 of the plaintiffs'
14 submission to the Court, there is a request that raises the
15 issue of asking for a Court order that the pharmacies named in
16 the PFS complete a DFS for these four cases, even though those
17 pharmacies aren't named as defendants either in the Master
18 Complaint or Short Form Complaint, and I think, based on this
19 discussion, that that request has been withdrawn and the
20 issues been resolved with the wholesalers, but I do want to
21 clarify that that is the case here. We don't see there being
22 an obligation for a pharmacy to complete a fact sheet if
23 they're not parties to a particular case, but I want to make
24 sure that that issue has been taken off the table for these
25 four cases.

1 MR. WILLIAMSON: Your Honor, if I may respond, this
2 is George Williamson again. I believe that our request is --
3 to the extent that a pharmacy defendant is in the MDL, in
4 other words, they've been sued in various cases, if they are
5 identified in a plaintiffs' fact sheet, even if they haven't
6 been sued in that particular case, we still believe that they
7 have an obligation to complete a fact sheet. No different
8 than a wholesaler who is not sued, frankly, in most cases,
9 when they're filed because plaintiff doesn't have the
10 information, but they're still required because they're in the
11 MDL to complete a fact sheet.

12 So we would ask the same of the pharmacy defendants
13 to the extent that they're in the MDL.

14 Now, where you have a mom and pop pharmacy that
15 hasn't been sued, they're not in the MDL, we don't believe
16 that at least at this point that the Court has the ability to
17 require them to complete a fact sheet, and to the extent that
18 that's an issue for any plaintiff, we can discuss directly
19 with that plaintiffs' attorney whether it makes sense to bring
20 the retailer into the case.

21 However, in situations where a pharmacy defendant is
22 already in the MDL, we would ask that they be required to
23 complete a fact sheet, even if they haven't been sued in a
24 particular plaintiffs' case.

25 MS. RICHER: Your Honor, this is Kristen Richer, also

1 on behalf of the pharmacy defendants. If I could just respond
2 to that point that Mr. Williamson made.

3 JUDGE VANASKIE: Yes.

4 MS. RICHER: Our position on this is one that we've
5 communicated via prior meet and confers, although we were not
6 aware that plaintiffs were planning to seek this relief in
7 their letter, but our position on this differs from
8 Mr. Williamson. Understanding that there are pharmacies who
9 are active in the MDL because they have been actually sued in
10 specific PI cases or in the class action complaint, and we do
11 not feel that it is fair or correct process-wise to require a
12 pharmacy who has not been sued in a personal injury Short Form
13 Complaint to respond to a defense fact sheet just based on
14 plaintiff having identified that pharmacy as a pharmacy who
15 dispensed Valsartan in Section 1 of the PFS.

16 If, you know, process-wise, the way that this should
17 work is that if plaintiffs, when they pull their pharmacy
18 records and they fill out their PFS decide that they're going
19 to identify a pharmacy in Section 1 of the PFS as having
20 dispensed Valsartan to a plaintiff, then plaintiff should
21 amend their Short Form Complaint to actually sue that pharmacy
22 if they want discovery from the pharmacy.

23 These are individual personal injury cases. There's
24 a reason that we have Short Form Complaints so that parties
25 know, are on notice that they're a defendant in the litigation

1 for that plaintiff, and if you don't, if that process is not
2 in place, then every pharmacy is going to have to look at
3 every PFS that's served and decide if they have to act like
4 they are a defendant in the case, despite not having been
5 named as a defendant in that case.

6 So it seems to me that the six years are relatively
7 simple if plaintiffs are concerned that this is an issue, then
8 they can amend their Short Form Complaint where applicable and
9 name the relevant pharmacy as defendant, and that solves the
10 problem, I think.

11 MR. WILLIAMSON: Your Honor, this is George
12 Williamson. If I may respond.

13 JUDGE VANASKIE: You may.

14 MR. WILLIAMSON: We are talking about four cases
15 here. We're not talking about every case in the MDL, we're
16 talking about --

17 MS. RICHER: Well, I think -- sorry, George, I didn't
18 mean to interrupt you. Go ahead.

19 MR. WILLIAMSON: We're talking about the four cases
20 that are currently at issue here. We're not talking about
21 every case in the MDL. In fact, the defendants only have to
22 complete a fact sheet for a total of 28 cases.

23 And to the extent that a pharmacy is already in the
24 MDL, the plaintiffs will identify where that situation has
25 happened and will communicate directly with the defendant who

1 is already in the MDL and request that they complete a
2 plaintiff fact sheet.

3 Now, I'm surprised that I've heard a defense counsel
4 suggest that we should sue the client, but I think the easier
5 way to do it is just to identify in the four cases where that
6 has occurred and reach out directly to those counsel and
7 request that a defense fact sheet be completed.

8 MS. RICHER: Well -- this is Kristen Richer again. I
9 want a direct distinction here. When we're talking about the
10 four cases that are getting thrown around, those are cases in
11 which it is my understanding, and this is based on my review
12 of the pleadings and the cases and the PFS, which are
13 pharmacies that have been identified in the PFS are not
14 defendants and are not participants in the litigation, and I
15 don't know if that's because they haven't been sued or what's
16 going on there.

17 So those are not active pharmacies. So we should
18 stop using those as being example of what active defendants
19 should be doing with respect to their PFS and DFS obligations
20 because are completely separately situated cases.

21 When we're talking about circumstances where you do
22 have an active defendant in the litigation, trying to
23 determine whether it needs to respond to discovery, I don't
24 think anyone should be surprised that a defendant wants to
25 have actually been sued in the case before they're forced to

1 respond to discovery in the case. That seems pretty par for
2 the course to me.

3 And so I don't think that's an unfair request. I
4 don't think it's a high burden for plaintiffs. They are the
5 masters of their pleadings and that, of course, applies to
6 individual plaintiffs in the litigation as well. These are
7 Short Form Complaints that should be amended and served for
8 relative use. If a party is an active defendant in the
9 litigation and we're simply asking for there to be a process,
10 because of the pretty ordinary process in litigation by which
11 parties are put on notice of claims against them so that they
12 know that they have to monitor discovery in those cases.

13 JUDGE VANASKIE: All right. I understand the
14 arguments. I would not require pharmacy defendants who are
15 not named in those four cases as defendants to prepare a
16 defense fact sheet. I think the better argument is that they
17 would have had to have been named, and if you have information
18 to suggest that they should be a defendant in the matter,
19 their Complaint should be amended to identify them as a
20 defendant in that particular matter.

21 But to ask pharmacy defendants who have not been
22 named to prepare defense fact sheets for cases in which they
23 are not parties, simply because they are a party in the
24 overall MDL is asking too much. So that's my determination on
25 that issue.

1 All right. Is there anything else to discuss today?

2 MR. NIGH: Yes, Your Honor, this is Daniel Nigh. I
3 wanted to raise an issue on timing of completion of defense
4 fact sheets before bellwether plaintiff depositions.

5 JUDGE VANASKIE: Go ahead.

6 MR. NIGH: So, you know, we've all understood from
7 the very beginning that one of the purposes is to be able to
8 understand, you know, how the product moved through the chain
9 of supply, and that was the reason -- one of the reasons for
10 the DFS from the outset. And so in understanding that, you
11 know, that's why we've always looked at it, need of the
12 pharmacy, the wholesaler, the finished dose manufacturer and
13 the API. So that's how this was presented.

14 So we actually need, you know, the whole chain of
15 DFSs before our plaintiffs' depositions pursue forward. In
16 terms of those four cases where pharmacies are not named, we
17 will revisit that issue, but we may have to move quickly in
18 terms of asking for leave to amend those Complaints.

19 But the larger issue is, you know, even on the four,
20 we get the wholesaler, we still have to have the finished dose
21 manufacturer DFS, and we still have to have the API
22 manufacturer DFS before those depositions can go forward, and
23 I think that's always been the understanding as we presented
24 the plan to have these ten bellwether plaintiff depositions go
25 forward first in the first timeframe, because those were the

1 ten that came from the set of 20 that were having DFSs worked
2 up since August of 2020.

3 And so that's why those can have an earlier date to
4 get their plaintiff depositions taken.

5 What I'm seeing more and more here, just in terms of,
6 you know, we understood that the wholesalers, you know, didn't
7 do an DFS and so because of that, the finished dose
8 manufacturers felt like that their DFS obligation wasn't
9 triggered, and then, of course, the APIs wouldn't have been
10 triggered at that point. So we're just --

11 JUDGE VANASKIE: Somebody is talking over somebody.
12 If you're not speaking, please mute your phone. Go ahead.

13 MR. NIGH: So in terms of the four, you know, we're
14 behind the ball. There's a lot of defense fact sheets to be
15 completed, because the wholesalers are starting now and they
16 -- even if they got it done in seven days, that gives the
17 finished dose manufacturer, they've got to get it done and
18 then the API got to get it done before plaintiff depositions.
19 That's always been the understanding, and so I just put that
20 out there. It's a heavy lift.

21 I mean, we're going to meet and confer with the
22 defendants on that, but that's going to be an issue. It's not
23 even just the four, though, it's the other six we still have
24 not received the API DFS, and so we wouldn't be able to move
25 forward with those plaintiffs' depositions until we get those

1 as well.

2 But my understanding is, we're going to try to
3 continue to work on that. However, we do -- I mean, we have
4 dates for plaintiff depositions but if we don't have those
5 DFSs, we're going to have to move those back.

6 So I wanted to make that aware at this point while we
7 were talking about timing and DFS issues.

8 JUDGE VANASKIE: Well, thanks for that, Mr. Nigh.
9 All I can say to you right now is that you all have to try to
10 coordinate, get together and coordinate the production of
11 those DFS so that depositions can proceed on schedule and
12 continue to raise the issue with me so that it can be
13 accomplished.

14 So if I'm hearing you correctly, Mr. Nigh, first, you
15 have to get the retailer and wholesale DFS -- DFSs, and then
16 you go up the chain; is that correct?

17 MR. NIGH: That's correct, and it may not be
18 contingent that we have to have the retailer to get the
19 wholesaler DFS done, but certainly from there, you know, the
20 finished dose manufacturers are going to likely need to have
21 the wholesalers' DFS and then the API manufacturer is going to
22 need to have the finished dose manufacturers' DFS. That's
23 correct.

24 JUDGE VANASKIE: Okay. All right. Well, all I can
25 urge is that you work cooperatively to get this accomplished.

1 Is there anything else now?

2 MR. DAVIS: Your Honor, John Davis for the
3 plaintiffs. Just one quick point of clarification, and I
4 believe this is what Your Honor contemplated with regard to
5 Mr. Trischler's submission on Monday, but plaintiffs' counsel
6 will be copied on that, correct?

7 JUDGE VANASKIE: Certainly.

8 MR. DAVIS: Thank you.

9 JUDGE VANASKIE: We're not talking about privileged
10 documents here, unless, Mr. Trischler, you determine that one
11 of those 12 documents sent to me was privileged. But, no, I
12 don't see any reason why you should not be copied on it.

13 MR. DAVIS: Thank you.

14 JUDGE VANASKIE: Anything else? All right. Thank
15 you all very much for your understanding today. Again, my
16 apologies for our late start, and I will be talking to you
17 next Wednesday, if not sooner. Thank you.

18 RESPONSE: Thank you, Your Honor.

19 (12:52 p.m.)

20 - - - - -

21

22 I certify that the foregoing is a correct transcript
23 from the record of proceedings in the above-entitled matter.

24

25 /S/ Karen Friedlander, CRR, RMR
Court Reporter/Transcriber

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